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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,237	04/17/2004	Daniel R. Burnett	35744-01110	9644

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EXAMINER	
WIEST, PHILIP R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
10/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,237	BURNETT, DANIEL R.	
	Examiner	Art Unit	
	Phil Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,33,35,36 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,33 and 35, 36, 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. In the reply filed 6/23/08, applicant amended claims 1 and 33, added new claim 38, and cancelled claims 5-7 and 37. Claims 1-7 and 12-38 are currently pending, and claims 12-32 and 34 are withdrawn from consideration.

Response to Arguments

2. Applicant's arguments with respect to the Rubenstein patent have been fully considered and are persuasive. Applicant's amendments to the claims overcome the rejection based on the embodiment of Figure 9. Therefore, the rejection of claim 1 has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of new interpretation of the Rubenstein patent.

3. Regarding the previous rejection, applicant also argues that it would not have been obvious to use an anti-infective coating on the pump of Rubenstein. Rubenstein clearly suggests the use of antibodies along the path of the shunt. Given this teaching, it is the examiner's opinion that one of ordinary skill in the art would have been motivated to coat any part of the device with an antibiotic coating. Furthermore, applicant merely claims an anti-infective coating, which is extremely broad. A coating of antibodies can be considered an anti-infective coating.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-4 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein et al. (US 6,264,625) in view of Buchwald (US 4,610,658). Rubenstein teaches an implantable fluid management system comprising a first tube member and second tube member attached to a pump 80. The pump further comprises an integrated controller (a plurality of check valves 86, 88) located inside the housing that control actuation of the pump (see Column 10), such that the system causes fluid to flow from a first body cavity to a second body cavity upon sufficient pressure differential. The valves are designed to function such that the pump is actuated when fluid pressures in the first and second body cavities exceed predetermined levels. The control valves are made of a biocompatible material. Rubenstein, however, does not specifically teach that the pump 80 is made of a biocompatible material and coated with an anti-infective coating.

Regarding Rubenstein's failure to specifically teach that the pump is made of a biocompatible material, Rubenstein clearly states that other aspects of the shunt (i.e. the conduit 2 and the valves 36) must be biocompatible because they are implanted in the body. Therefore, it is obvious that the pump and its housing should be made of a similar biocompatible material because physiological fluids also contact the pump. It is

the examiner's opinion that one of ordinary skill in the art at the time of invention would have been motivated to provide a biocompatible pump housing in order to minimize the impact of the shunt on the body.

Regarding Rubenstein's failure to specifically teach an anti-infective coating, Buchwald teaches a shunt for transferring fluids between two body cavities comprising a pump. The pump may be coated with a number of materials that prevent infections within the body (Column 8, Lines 13-41). Because applicant does not claim a specific anti-infective coating, any coating that substantially prevents infection may be considered an anti-infective coating. Anti-infective coatings are commonly used in the art of physiological fluid transfer in order to prevent infections from occurring as a result of the shunt being implanted in the body. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the fluid shunt of Rubenstein with the anti-infective coating of Buchwald in order to substantially prevent infections from forming as a result of the shunt's implantation.

5. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein in view of Buchwald, and further in view of Burbank (US 6,193,684). Rubenstein and Buchwald reasonably suggest the device of Claim 1 substantially as claimed, and Rubenstein further teaches anchoring means 76 for anchoring the pump housing to a designated part of the body (see Figures (10D and 10E). Rubenstein and Buchwald, however, do not specifically disclose that the Burbank discloses an

implantable physiological fluid shunt that is anchored to the abdominal wall of a patient using adhesives, staples, sutures, or any other known attachment method (Column 5, Lines 23-43). As is established in the art, the attachment of the device to the abdominal wall prevents migration of the device, thereby ensuring that fluid flow from the body cavity is not interrupted. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to one of ordinary skill in the art to modify the fluid management system of Rubenstein with the use of staples, adhesive, or other known attachment means of Burbank in order to securely attach the housing of the device to a location nearby the fluid transfer location, thereby preventing fluid communication from being interrupted by shunt migration.

6. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein in view of Buchwald, and further in view of Gorsuch (5,980,478). Rubenstein and Buchwald reasonably suggest the device of Claim 1, but do not specifically disclose that the system comprises a material that promote fibrotic ingrowth and prevent bacterial adhesion to the device. Gorsuch discloses an implantable fluid transfer shunt that comprises an anti-infective coating that prevents bacteria adhesion to the housing, thereby reducing the risk of infection (Column 2, Line 55 through Column 3, Line 1). Gorsuch further discloses a fibrous cuff 26 that provides a substrate for tissue ingrowth. The ingrowth of tissue prevents foreign bacteria from entering the housing and helps to anchor the housing in place (Column 3, Lines 1-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to

modify the fluid management system of Rubenstein and Buchwald with the use of anti-infective coatings and fibrotic ingrowth-promoting materials of Gorsuch in order to reduce the risk of bacterial buildup inside the device and provide further anchoring means.

7. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein in view of Buchwald, and further in view of Treu et al. (US 6,254,567). Rubenstein and Buchwald reasonably suggest the device of Claim 1 substantially as claimed, and Rubenstein further teaches the use of a pressure sensor at the end of the inlet tube, such that pressure may be monitored such that a signal is sent to the controller to initiate fluid flow at a predetermined pressure. Rubenstein and Buchwald, however, do not specifically teach or suggest that the system comprises pressure sensors at both ends of the shunt. Treu teaches a system for the treatment of physiological fluid comprising a fluid line having an inlet tube 62 and an outlet tube 72. The inlet and outlet tubes comprise pressure sensors (76, 78) at both ends thereof that send pressure data to a controller 16. The controller analyzes the sensed pressures and regulates a pump to maintain a predetermined pressure differential and flow rate through the system. If sensed pressures fall outside of a predetermined range, the pump will stop entirely. See Column 6, Lines 14-24. It is well known in the art of fluid transfer that monitoring pressure at both ends of the tube, flow rate and pressure may be more accurately controlled by a pump. Knowing the pressure differential between two body cavities will provide more feedback than simply knowing the inlet pressure,

thereby allowing more precise flow rate monitoring and control. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the fluid transfer shunt of Rubenstein and Buchwald with the inlet and outlet pressure sensors of Treu in order to more accurately control the flow of fluid through the shunt.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761